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Docket No.: 00630/0204187-US0
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**In re Patent Application of:
Scott Alan Jelinsky et al.**

Application No.: 10/511,064

Confirmation No.: 8561

Filed: April 20, 2005

Art Unit: 1639

For: ESTROGEN RECEPTOR ALPHA
REGULATED GENE EXPRESSION
RELATED ASSAYS AND THERAPEUTICS

Examiner: J. S. Lundgren

INFORMATION DISCLOSURE STATEMENT (IDS)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed more than three months after the U.S. filing date, OR more than three months after the date of entry of the national stage of a PCT application, AND after the mailing date of the first Office Action on the merits, whichever occurs first, but before the mailing date of a Final Office Action or Notice of Allowance (37 CFR 1.97(c)).

Applicant has not submitted copies of each cited U.S. patent and U.S. patent application as required by 37 CFR 1.98(a)(2)(i), amended October 2004, as the U.S. Patent and Trademark

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Office has waived this requirement for all U.S. patent applications. Applicant submits herewith copies of foreign and non-patents in accordance with 37 CFR 1.98(a)(2).

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Information Disclosure statement shall not be construed to be an admission that any patent, publication or other information referred to therein is “prior art” for this invention unless specifically designated as such.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

Our check in the amount of \$180.00 covering the fee set forth in 37 CFR 1.17(p) is enclosed. The Commissioner is authorized to charge any deficiency of up to \$300.00 or credit any excess in this fee to Deposit Account No. 04-0100.

Dated: June 23, 2006

Respectfully submitted,

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)			Application Number	10/511,064-Conf. #8561	
			Filing Date	April 20, 2005	
			First Named Inventor	Scott Alan Jelinsky	
			Art Unit	1639	
			Examiner Name	J. S. Lundgren	
Sheet	1	of	4	Attorney Docket Number	00630/0204187-USO

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	AA*	US-5,508,164	04-16-1996	Kausch	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ³
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				

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NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	CA	Grodstein, F., Manson, J. E., Colditz, G. A., Willett, W. C., Speizer, F. E. & Stampfer, M. J. (2000); A prospective, observational study of postmenopausal hormone therapy and primary prevention of cardiovascular disease. <i>Annals of Internal Medicine</i> 133, 933-41.	
	CB	Barrett-Connor, E., Slone, S., Greendale, G., Kritz-Silverstein, D., Espeland, M., Johnson, S. R., Wacławski, M. & Fineberg, S. E. (1997); The postmenopausal estrogen/progestin interventions study: primary outcomes in adherent women. <i>Maturitas</i> 27, 261-74.	
	CC	Godsland, I. F. (2001); Effects of postmenopausal hormone replacement therapy on lipid, lipoprotein, and apolipoprotein (a) concentrations: analysis of studies published from 1974-2000. <i>Fertility & Sterility</i> 75, 898-915.	
	CD	Nanda, K., Bastian, L. A., Hasselblad, V. & Simel, D. L. (1999); Hormone replacement therapy and the risk of colorectal cancer: a meta-analysis. <i>Obstetrics & Gynecology</i> 93, 880-8.	
	CE	Kawas, C., Resnick, S., Morrison, A., Brookmeyer, R., Corrada, M., Zonderman, A., Bacal, C., Lingle, D. D. & Metter, E. (1997); A prospective study of estrogen replacement therapy and the risk of developing Alzheimer's disease: the Baltimore Longitudinal Study of Aging. <i>Neurology</i> 48, 1517-21.	
	CF	Worzala, K., Hiller, R., Sperduto, R. D., Mutalik, K., Murabito, J. M., Moskowitz, M., D'Agostino, R. B. & Wilson, P. W. (2001); Postmenopausal estrogen use, type of menopause, and lens opacities: the Framingham studies. <i>Archives of Internal Medicine</i> 161, 1448-54.	
	CG	Kuiper, G. & Carlsson, B., Grandien, K., Enmark, E., Haggblad, J., Nilsson, S. & Gustafsson, J. A. (1997) <i>Endocrinology</i> 138, 863-70.	
	CH	Hill, A. A., Hunter, C. P., Tsung, B. T., Tucker-Kellogg, G & Brown, E. L. (2000); Genomic analysis of gene expression in <i>C. elegans</i> . <i>Science</i> 290, 809-12.	
	CI	Shughrue, P., Scrimo, P., Lane, M., Askew, R. & Merchenthaler, I. (1997); The distribution of estrogen receptor-beta mRNA in forebrain regions of the estrogen receptor-alpha knockout	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Complete if Known

Application Number	10/511,064-Conf. #8561
Filing Date	April 20, 2005
First Named Inventor	Scott Alan Jelinsky
Art Unit	1639
Examiner Name	J. S. Lundgren
Attorney Docket Number	00630/0204187-USO

Sheet	2	of	4
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		mouse. Endocrinology 138, 5649-52.	
CJ	Evans, M. J., Eckert, A., Lai, K., Adelman, S. J. & Hamish, D. C. (2001); Reciprocal antagonism between estrogen receptor and NF-kappaB activity in vivo. Circulation Research 89, 823-830.		
CK	Kraichely, D. M., Sun, J., Katzenellenbogen, J. A. & Katzenellenbogen, B. S. (2000); Conformational changes and coactivator recruitment by novel ligands for estrogen receptor-alpha and estrogen receptor-beta: correlations with biological character and distinct differences among SRC coactivator family members. Endocrinology 141, 3534-45.		
CL	Lubahn, D. B., Moyer, J. S., Golding, T. S., Couse, J. F., Korach, K. S. & Smithies, O. (1993); Alteration of reproductive function but not prenatal sexual development after insertional disruption of the mouse estrogen receptor gene. Proceedings of the National Academy of Sciences of the United States of America 90, 11162-6.		
CM	Pendaries, C., Darblade, B., Rochaix, P., Krust, A., Chambon, P., Korach, K. S., Bayard, F. & Arnal, J. F. (2002); The AF-1 activation-function of ERalpha may be dispensable to mediate the effect of estradiol on endothelial NO production in mice. Proceedings of the National Academy of Sciences of the United States of America 99, 2205-2210.		
CN	Couse, J. F., Curtis, S. W., Washburn, T. F., Lindzey, J., Golding, T. S., Lubahn, D. B., Smithies, O. & Korach, K. S. (1995); Analysis of transcription and estrogen insensitivity in the female mouse after targeted disruption of the estrogen receptor gene. Molecular Endocrinology 9, 1441-54.		
CO	Berry, M., Metzger, D. & Chambon, R (1990); Role of the two activating domains of the oestrogen receptor in the cell-type and promoter-context dependent agonistic activity of the anti-oestrogen 4-hydroxytamoxifen. EMBO Journal 9, 2811-8.		
CP	Hall, J. M. & McDonnell, D. P. (1999); The estrogen receptor beta-isoform (ERbeta) of the human estrogen receptor modulates ERalpha transcriptional activity and is a key regulator of the cellular response to estrogens and antiestrogens. Endocrinology 140, 5566-78.		
CQ	Weihua, Z., Saji, S., Makinen, S., Cheng, G., Jensen, E. V., Waamer, M. & Gustafsson, J. A. (2000); Estrogen receptor (ER) beta, a modulator of ERalpha in the uterus. Proceedings of the National Academy of Sciences of the United States of America 97, 5936-41.		
CR	Trogan, E., Choudhury, R. P., Dansky, H. M., Rong, J. X., Breslow, J. L. & Fisher, E. A. (2002); Laser capture microdissection analysis of gene expression in macrophages from atherosclerotic lesions of apolipoprotein E-deficient mice. Proceedings of the National Academy of Sciences of the United States of America 99, 2234-2239.		
CS	Evans, M. J., Lai, K., Shaw, L. J., Harnish, D. C. & Chadwick, C. C. (2002); Estrogen receptor alpha inhibits IL-1beta induction of gene expression in the mouse liver. Endocrinology, 143(7):2559-70.		
CT	McIntire, J. J., Umetsu, S. E., Akbari, O., Potter, M., Kuchroo, V. K., Barsh, G. S., Freeman, Q. J., Umetsu, D. T. & DeKruyff, R. H. (2001); Identification of Tapr (an airway hyperreactivity regulatory locus) and the linked Tim gene family. Nature Immunology 2, 1109-16.		
CU	Ichimura, T., Bonventre, J. V., Bailly, V., Wei, H., Hession, C. A., Cate, R. L. & Sanicola, M. (1998); Kidney injury molecule-1 (KIM-1), a putative epithelial cell adhesion molecule containing a novel immunoglobulin domain, is up-regulated in renal cells after injury. Journal of Biological Chemistry 273, 4135-42.		
CV	Davidoff, M., Caffier, H. & Schiebler, T. H. (1980); Steroid hormone binding receptors in the rat kidney. Histochemistry 69, 39-48.		
CW	Aitken, J. M., Lindsay, R. & Hart, D. M. (1974); The redistribution of body sodium in women on		

Examiner Signature		Date Considered	
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PTO/SB/08a/b (07-05)

Approved for use through 07/31/2006. OMB 0651-0031
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)		Complete if Known			
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		Examiner Name	J. S. Lundgren		
Sheet	3	of	4	Attorney Docket Number	00630/0204187-USO

		long-term oestrogen therapy. Clinical Science & Molecular Medicine 47, 179-87.	
	CX	Pirani, B. B., Campbell, D. M. & MacGillivray, I. (1973); Plasma volume in normal first pregnancy. Journal of Obstetrics & Gynaecology of the British Commonwealth 80, 884-7.	
	CY	Stachenfeld, N. S., DiPietro, L., Palter, S. F. & Nadel, E. R. (1998); Estrogen influences osmotic secretion of AVP and body water balance in postmenopausal women. American Journal of Physiology 274, R187-95.	
	CZ	Verlander, J. W., Tran, T. M., Zhang, L., Kaplan, M. R. & Hebert, S. C. (1998); Estradiol enhances thiazide-sensitive NaCl cotransporter density in the apical plasma membrane of the distal convoluted tubule in ovariectomized rats. Journal of Clinical Investigation 101, 1661-9.	
	CA1	Farmer, M. K., Robbins, M. J., Medhurst, A. D., Campbell, D. A., Ellington, K., Duckworth, M., Brown, A. M., Middlemiss, D. N., Price, G. W. & Pangalos, M. N. (2000); Cloning and characterization of human NTT5 and v7-3: two orphan transporters of the Na ⁺ /Cl ⁻ -dependent neurotransmitter transporter gene family. Genomics 70, 241-52.	
	CB1	Reddy, M. M., Light, M. J. & Quinton, P. M. (1999); Activation of the epithelial Na ⁺ channel (ENaC) requires CFTR Cl ⁻ channel function. Nature 402, 301-4.	
	CC1	Fu, G. K., Lin, D., Zhang, M. Y., Bikle, D. D., Shackleton, C. H., Miller, W. L. & Portale, A. A. (1997); Cloning of human 25-hydroxyvitamin D-1 alpha-hydroxylase and mutations causing vitamin D-dependent rickets type 1. Molecular Endocrinology 11, 1961-70.	
	CD1	Tanaka, Y., Castillo, L. & DeLuca, H. F. (1976); Control of renal vitamin D hydroxylases in birds by sex hormones. Proceedings of the National Academy of Sciences of the United States of America 73, 2701-5.	
	CE1	McKane, W. R., Khosla, S., Burritt, M. F., Kao, P. C., Wilson, D. M., Ory, S. J. & Riggs, B. L. (1995); Mechanism of renal calcium conservation with estrogen replacement therapy in women in early postmenopause--a clinical research center study. Journal of Clinical Endocrinology & Metabolism 80, 3458-64.	
	CF1	Grey, A. B., Stapleton, J. P., Evans, M. C., Tatnell, M. A. & Reid, I. R. (1996); Effect of hormone replacement therapy on bone mineral density in postmenopausal women with mild primary hyperparathyroidism. A randomized, controlled trial. Annals of Internal Medicine 125, 360-8.	
	CG1	Johnson, J. A. & Kumar, R. (1994); Renal and intestinal calcium transport: roles of vitamin D and vitamin D-dependent calcium binding proteins. Seminars in Nephrology 14, 119-28.	
	CH1	Hajjar, K. A. (2001); Homocysteine: a sulph'rous fire. Journal of Clinical Investigation 107, 663-4.	
	CI1	Bostom, A. G., Silbershatz, H., Rosenberg, I. H., Selhub, J., D'Agostino, R. B., Wolf, P. A., Jacques, P. F. & Wilson, P. W. (1999); Nonfasting plasma total homocysteine levels and all-cause and cardiovascular disease mortality in elderly Framingham men and women. Archives of Internal Medicine 159, 1077-80.	
	CJ1	Walsh, B. W., Paul, S., Wild, R. A., Dean, R. A., Tracy, R. P., Cox, D. A. & Anderson, P. W. (2000); The effects of hormone replacement therapy and raloxifene on C-reactive protein and homocysteine in healthy postmenopausal women: a randomized, controlled trial. Journal of Clinical Endocrinology & Metabolism 85, 214-8.	
	CK1	Libert, F., Parmentier, M., Lefort, A., Dumont, J. E. & Vassart, G. (1990); Complete nucleotide sequence of a putative G protein coupled receptor: RDC1. Nucleic Acids Research 18, 1917.	
	CL1	Kapas, S. & Clark, A. J. (1995); Identification of an orphan receptor gene as a type 1 calcitonin gene-related peptide receptor. Biochemical & Biophysical Research Communications 217, 832-8.	

Examiner Signature		Date Considered	
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**INFORMATION DISCLOSURE
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Filing Date	April 20, 2005
First Named Inventor	Scott Alan Jelinsky
Art Unit	1639
Examiner Name	J. S. Lundgren
Attorney Docket Number	00630/0204187-USO

CM1	Gangula, P. R., Zhao, H., Wimalawansa, S. J., Supowit, S. C., DiPette, D. J. & Yallampalli, C. (2001); Pregnancy and steroid hormones enhance the systemic and regional hemodynamic effects of calcitonin gene-related peptide in rats. <i>Biology of Reproduction</i> 64, 1776-83.
CN1	Cadnapaphomchai, M. A., Briner, V. A. & Schrier, R. W. (2001) in <i>Diseases of the Kidney and Urinary Tract</i> , ed. Schrier, R. W. (Lippincott Williams & Wilkins, Philadelphia), pp. 1459-1487.
CO1	Safe, S. (2001); Transcriptional activation of genes by 17 beta-estradiol through estrogen receptor-Sp1 interactions. <i>Vitamins & Hormones</i> 62, 231-52.
CP1	Paech, K., Webb, P., Kuiper, G. G., Nilsson, S., Gustafsson, J., Kushner, P. J. & Scanlan, T. S. (1997); Differential ligand activation of estrogen receptors ERalpha and ERbeta at AP1 sites. <i>Science</i> 277, 1508-10.
CQ1	Naka, T., Fujimoto, M. & Kishimoto, T. (1999); Negative regulation of cytokine signaling: STAT-induced STAT inhibitor. <i>Trends in Biochemical Sciences</i> 24, 394-8.
CR1	Melia, M.J., Bofill, N., Hubank, M., Meseguer A. (1998); Identification of Androgen-Regulated Genes in Mouse Kidney by Representational difference Analysis and Random Arbitrarily Primed Polymerase Chain Reaction. <i>Endocrinology</i> , 139:688-695.
CS1	Chern, T.H., Chiang, F-T., Wu, K-D, Hsu, K-L, Lo, H-M, Tseng, C-D., and Tseng, Y-Z. (2000); Expression Pattern in a Modified Equalized Kidney cDNA Library of Hypertensive Rat. <i>Nephron</i> , 85:258-266.
CT1	WO/03/087336 Search Report

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

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Application No. (if known): 10/511,064

Attorney Docket No.: 00630/0204187-US0

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